

天津九安医疗电子股份有限公司

FEB 27 2009

Andon Health Co., Ltd.

地址: 天津市南开区雅安道金平路 10 号华侨创业大厦 7 楼

Add: 7th floor Hua Qiao Chuang Ye Plaza, No. 10 JinPing Road, Ya An Road, NanKai District, Tianjin, China

邮编 (P.C.): 300190

电话 (Tel): 86-22-6052 6161

传真 (Fax): 86-22-6052 6162

E-mail: andon@public.tpt.tj.cn

## 510(k) Summary

### Identification of the submitter:

Submitter: Andon Health Co., Ltd.  
No 31, Changjiang Road, Nankai District, Tianjin,  
P.R. China, 300193

Telephone number: 86-22-6052 6161

Fax number: 86-22-6052 6162

Contact: Liu Yi

Date of Application: 11/10/08

### Identification of the product:

Device proprietary Name: Arm Electronic Blood Pressure Monitor

Common name: Noninvasive blood pressure measurement systems

Classification name: Noninvasive blood pressure measurement system  
Class II per 21 CFR 870.1130

### Marketed Devices to which equivalence is claimed:

<u>Device</u>	<u>manufacture</u>	<u>510(k) number</u>
KD-322	Andon Health Co., Ltd	K052676
KD-622	Andon Health Co., Ltd	K030358
KD-525E	Andon Health Co., Ltd	K070395
KD-575	Andon Health Co., Ltd	K042418
KD-593	Andon Health Co., Ltd	K070828
KD-595	Andon Health Co., Ltd	K070828
KD-596	Andon Health Co., Ltd	K070828
KD-598	Andon Health Co., Ltd	K070828

### Device description:

Arm Electronic Blood Pressure Monitor (Models: KD-322, KD-622, KD-575, KD-525E, KD-593, KD-595, KD-596, KD-598) is Non-invasive blood pressure measurement system for only one person each time. Based on oscillometric and silicon integrate pressure sensor technology, the device is used to monitor systolic, diastolic blood pressure and pulse rate which will be shown on a LCD

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with an electronic interface module. Buckling a cuff around the left upper arm, which cuff circumference is limited to 22cm-48cm (be comprised of 3 cuffs, 22cm-30cm, 30cm-42cm, 42cm-48cm, select one), the device can analyze the signals promptly and display the test results.

**Intended use:**

Arm Electronic Blood Pressure Monitor (Models: KD-322, KD-622, KD-575, KD-525E, KD-593, KD-595, KD-596, KD-598) is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate of adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual, which is same as predicated device.

**Summary comparing technological characteristics with predicate device:**

Arm Electronic Blood Pressure Monitor (Models: KD-322, KD-622, KD-575, KD-525E, KD-593, KD-595, KD-596, KD-598) has the same principle with predicated device, which utilizes Oscillometric measurement method to monitor the blood pressure and the result can be shown on the LCD.

The modifications that were made are:

(1): Cuff size change into 22cm-48cm from 22cm-30cm.

(2): The Environmental parameters are changed.

The operational range for humidity (<90%) and the storage range for temperature ( - 20-55°C) and for humidity (<95%) of the modified device are all changed from the predict device.

(3): The Cuff Pressure Range change into 0-300mmHg from 20-300 mmHg (only for KD-322, KD-622 and KD-575).

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Please find the following tabulated comparison supporting that the proposed device is substantially equivalent to the predicated device.

FDA file reference number	Predicated Devices
Technological Characteristics	Comparison result
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Identical
Performance	Identical
Sterility	Not Applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Not Applicable
Energy used and/or delivered	Identical
Where used	Similar
Standards met	Identical
Electrical safety	Identical

**Device testing:**

Arm Electronic Blood Pressure Monitor (Models: KD-322, KD-622, KD-575, KD-525E, KD-593, KD-595, KD-596, KD-598) meets the following standards:

- ANSI/AAMI SP-10 standard
- EN60601-1 Medical electrical equipment Part 1: General requirements for safety
- EN60601-1-2 Electromagnetic Compatibility



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 27 2009

Andon Health Co. Ltd.  
c/o Ms. Liu Yi  
No. 31, Changjiang Road, Nankai District  
Tianjin, P.R. China 300193

Re: K083395

Trade Name: Arm Electronic Blood Pressure Monitor, Models KD-322, KD-622, KD-575,  
KD-525E, KD-593, KD-595, KD-596 and KD-598

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: Class II (two)

Product Code: DXN

Dated: February 4, 2009

Received: February 9, 2009

Dear Ms. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

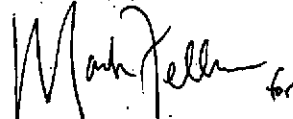
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

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Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

天津九安医疗电子股份有限公司

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## Statement of Indications for Use

510(k) Number: K083395

Applicant: Andon Health Co., Ltd

Device name: Arm Electronic Blood Pressure Monitor  
Models: KD-322, KD-622, KD-575, KD-525E, KD-593,  
KD-595, KD-596, KD-598

### Indications for use:

Arm Electronic Blood Pressure Monitor (Models: KD-322, KD-622, KD-575, KD-525E, KD-593, KD-595, KD-596, KD-598) is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm (be comprised of 3 cuffs, 22cm-30cm, 30cm-42cm, 42cm-48cm, select one).

Prescription use \_\_\_\_\_ AND/OR Over-The-Counter Use YES  
Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mah Jellum  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K083395